K020584

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neptec

ISO 9001 Registered

510(k) Summary

Submitter

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Contacts

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or

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Date Prepared

February 18, 2002

Device Information

Trade Name: CareCompanion Nurse Station / CareCompanion Patient Station

Common Name: Tele Homecare System

Classification Name: Radiofrequency Physiological Signal Transmitter and Receiver

Device Description

The CareCompanion System consists of two components: a transportable Patient Station installed typically in a patient's home; and the Nurse Station, installed in a healthcare provider or professional caregiver's office. The two components communicate with each other through modems over standard telephone lines and transmit real-time video, audio and data between them.

The real-time video and audio communications allow the patient and the caregiver to view and speak with each other.

With existing legally marketed vital signs measurement devices integrated with the Patient Station, the Patient Station is designed to monitor the patient's blood pressure, pulse rate, blood glucose level, weight and/or heart, lung and bowel sounds, and transmit this data to the Nurse Station. The data is displayed to the caregiver operating the Nurse Station and also automatically recorded in a patient information database. The heart, lung and bowel sounds may be listened to by the caregiver using a set of headphones supplied with the system.

Vital signs measurement devices integrated in the CareCompanion are FDA approved devices and are used for the same purposes for which they received 510(k) approval. The Patient Station may be configured for use with one to four devices.

The Nurse Station consists of two sub-components, the Nurse Station PC, which is a standard PC with supporting peripherals connected to a videophone, which provides the video conferencing functions for the Nurse Station. The Nurse Station PC may also operate as a standalone device for patient data management and record keeping functions.

Substantial Equivalence

The Neptec CareCompanion is substantially equivalent to the following predicate systems: the N2000 Base Station / N2001 Nurse Station (#K012801) by Neptec Design Group Ltd, the Electronic HouseCall System (#K000237) by Cybercare, Inc., and the Aviva Systems (#K981533) by American Telecare, Inc.

The CareCompanion and its predicate systems have the same general use to provide the capability for health care professionals to monitor the vitals signs of some of their patients from remote locations.

The main functional differences between the systems are that the predicate devices provide the capability to generate higher resolution images allowing heath care professionals to perform a range of assessment functions including wound care. This feature is not an indicated use for the CareCompanion. The Electronic HouseCall System by Cybercare is also capable of communicating over ISDN, DSL or Internet links in addition to standard telephone lines. These differences, however, are not significant with regard to performance or safety of the vital signs data monitoring and collection functions.

Intended Use

The Patient Station is intended to be used upon prescription of an authorized healthcare provider by patients as a means to collect and transmit patient vital signs information over standard telephone lines between the patient, typically at home, and a health care professional at the health care provider's site. The information includes: blood

pressure, pulse rate, blood glucose level, weight, and heart, lung and bowel sounds. The information is collected upon request and direction of the healthcare provider.

The CareCompanion Patient Station is intended to be used in conjunction with the CareCompanion Nurse Station to provide two-way video, audio and data communications between the patient and the health care professional.

The device does not send any real-time alarms. The device a diagnostic aid. Clinical judgement and experience are required to check and interpret the information transmitted. The device is not intended as a substitute for medical care. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

Performance Testing

Testing was performed to validate the functional performance of the CareCompanion. In particular, testing was performed with each vital signs measurement device to show that they operate equivalently when integrated with CareCompanion as when operated as independent devices.

In addition, the CareCompanion Patient Station and the CareCompanion Nurse Station have been subjected to performance testing to applicable mechanical, electrical and environmental standards.

Conclusion

The results of the test indicate that the device is substantially equivalent to its predicate devices and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2 2002

Mr. John Schneider
HINS Project Manager
Neptec Design Group Ltd.
302 Legget Drive
Kanata, Ontario
Canada K2K 1Y5

Re: K020584
Trade Name: CareCompanion Nurse Station and CareCompanion Patient Station
Regulation Name: Noninvasive Blood Pressure Measurement System and Glucose Test System
Regulation Number: 870.1130 and 862.1345
Regulatory Class: Class II (two)
Product Code: DXN and CGA
Dated: February 18, 2002
Received: February 21, 2002

Dear Mr. Schneider:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

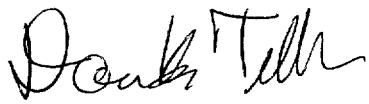
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: CareCompanion Nurse Station / CareCompanion Patient Station

Indications For Use:

The CareCompanion Patient Station is intended to be used in conjunction with the CareCompanion Nurse Station to provide two-way video, audio and data communications between the patient and the health care professional.

The CareCompanion Patient Station is used upon prescription of an authorized healthcare provider by patients where regular monitoring of vital signs information is indicated. The information is collected from the CareCompanion Patient Station and transmitted over standard telephone lines to a health care professional.

The device does not send any real-time alarms. The device a aid. Clinical judgement and experience are required to check and interpret the information transmitted. The device is not intended as a substitute for medical care. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020584